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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,929	10/31/2003	Arkady Kokish	ACSC 64781 (4150P)	2993
24201	7590	11/01/2007		
FULWIDER PATTON LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE, TENTH FLOOR LOS ANGELES, CA 90045			EXAMINER OMGBA, ESSAMA	
			ART UNIT 3726	PAPER NUMBER
			MAIL DATE 11/01/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/698,929	KOKISH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Essama Omgba	3726	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,7 and 9-15 is/are rejected.
- 7) ☒ Claim(s) 3-6 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/10/2007</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The indicated allowability of claims 1-14 is withdrawn in view of the newly discovered reference(s) to Gonzales et al. (US Patent 6,683,757). Rejections based on the newly cited reference(s) follow.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the tube comprising "an outer layer of a first polymer, and an inner layer extending at least along the length of the tubular layer and formed of a second polymer having a higher coefficient of friction than the outer layer" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, and 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Gonzales et al. (US Patent 6,863,757).

With regards to claims 1 and 13, Gonzales et al. discloses a method of making a polymeric tubular layer of an expandable medical device or component comprising placing a polymeric tubular layer 10 having a length in a lumen of a tube 14, the polymeric tubular layer in the lumen disposed on a mandrel 12 (fig. 3A), longitudinally stretching the tube to a stretch configuration and restraining the tube in the stretched configuration (col. 6, lines 24-32 and 49-53), unrestraining the tube to release the tube from the stretched configuration so that the length of the tube decreases and thereby longitudinally compresses the polymeric tubular layer, detaching the tube from the compressed polymeric tubular layer and removing the compressed tubular layer from the lumen of the tube and from the mandrel, to form the polymeric tubular layer of the

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expanded medical device (col. 2, lines 49-53 and col. 6, lines 56-61). Applicant should note that the tube is attached in the stretched configuration to the polymeric tubular layer when the tube is heated and radially shrinks. Also the invention as disclosed by Gonzales et al. could be used for making a catheter having a balloon (col. 2, lines 53-56 and col. 9, lines 27-30).

For claim 2, Applicant should note a radially inward force is provided to the tube as a result of heat shrinking in the radial direction.

For claim 10, see column 7, lines 4-6.

For claims 11 and 14, see column 8, lines 54-58.

For claim 12, Applicant should note such recited steps are conventional in the art.

For claim 15, see column 2, lines 47-49.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzales et al.

With regards to claim 7, Gonzales et al. discloses a method of making a polymeric tubular layer of an expanded medical device as shown above. Although

Gonzales et al. does not specifically disclose the elastomer polymer tube being stretched at least about 120%, however Gonzales et al. discloses that the polymeric tube can be stretched by a specific amount to provide a heat shrink tube which axially shrinks by a desired amount (col. 3, lines 29-33). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided such stretching percentage in the method of Gonzales et al., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art.

For claim 9, Applicant should note that it is within the general knowledge of one of ordinary in the art to repeat the method steps as needed in order to achieve a desired compaction of the tubular layer.

#### ***Allowable Subject Matter***

7. Claims 3-6 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

8. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on August 10, 2007 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS**

**MADE FINAL.** See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Essama Omgba whose telephone number is (571) 272-4532. The examiner can normally be reached on M-F 9-6:30, 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Bryant can be reached on (571) 272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Essama Omgba  
Primary Examiner  
Art Unit 3726

eo  
October 29, 2007